

Notice of Allowability

Application No.

09/988,115

Examiner

Deborah Crouch, Ph.D.

Applicant(s)

ROBL ET AL.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the RCE filed Aug. 5, the letter filed Sep. 23, and the interview summary 9/28, all 2005.
2. ☒ The allowed claim(s) is/are 1,3,4,10,12,21,23,26,28,51,54,57,60,66,68,70-72 and 76.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 8/5/05, 1/31/05
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 9/28/05
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____



Deborah Crouch, Ph.D.
Primary Examiner
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An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Karen Elbing on September 28, 2005.

1. Please rewrite claims 1, 21, 26, 66, 68 and 76 as follows:

1. A transgenic bovine whose cells comprise one or more artificial chromosomes, each artificial chromosome comprising one or more human immunoglobulin heavy or light chain loci that undergo rearrangement and are expressed in B-cells to produce a human immunoglobulin in response to exposure to one or more antigens.

10. An isolated transgenic bovine B-cell comprising one or more artificial chromosomes, each artificial chromosome comprising one or more human immunoglobulin heavy or light chain loci that undergo rearrangement and are expressed to produce a human immunoglobulin in response to exposure to one or more antigens.

21. A method of producing human antibodies, said method comprising the steps of: (a) administering one or more antigens of interest to a transgenic bovine whose cells comprise one or more artificial chromosomes, each artificial chromosome comprising one or more human immunoglobulin heavy or light chain loci that undergo rearrangement and are expressed in B-cells, resulting in production of human antibodies against said one or more antigens; and (b) recovering said human antibodies from said bovine.

26. A method of producing human antibodies to one or more antigens, said method comprising recovering human antibodies from a transgenic bovine whose cells

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comprise one or more artificial chromosomes, each artificial chromosome comprising one or more human immunoglobulin heavy or light chain loci that undergo rearrangement and are expressed in B-cells, resulting in production of human antibodies against said one or more antigens.

66. The transgenic bovine of claim 1, wherein said immunoglobulin loci comprise both a human immunoglobulin light chain locus and human immunoglobulin heavy chain locus.

68. The cell of claim 10, wherein said immunoglobulin loci comprise both a human immunoglobulin light chain locus and human immunoglobulin heavy chain locus.

76. An isolated B-cell obtained from a transgenic bovine of claim 1, wherein the B-cell comprises one or more artificial chromosomes, each artificial chromosome comprising one or more human immunoglobulin loci that undergo rearrangement and are expressed to produce a human immunoglobulin in response to exposure to one or more antigens.

2. Cancel claims 2, 11, 24, 49, 50, 52, 53, 59, 61-65, 67, 69 and 73-75

3. Rewrite the title as:

--Transgenic Bovine Comprising Human Immunoglobulin Loci and Producing Human Immunoglobulin--.

The following is an examiner's statement of reasons for allowance: The letter filed September 23, 2005 finalizing the conditions for the deposit of Δ HAC and $\Delta\Delta$ HAC makes claims 4 and 70-72 allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany

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the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Fri, 7:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deborah Crouch, Ph.D.
Primary Examiner
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September 29, 2005